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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,448	08/07/2002	Lilian Fuchshuber	468452000200	1448

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EXAMINER

VENKAT, JYOTHSNA A

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/069,448	<b>Applicant(s)</b> FUCHSHUBER ET AL.	
	<b>Examiner</b> JYOTHSNA A. VENKAT Ph. D	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-10, 12-16 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-10, 12-16, and 18-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/17/05 has been entered.

Claims 1-6, 8-10, 12-16 and 18-22 are pending in the application and the status of the application is as follows:

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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3. Claims 1-6; 8-10, 12-16 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of U. S. Patent '152 and WO 87/04617('617) and U. S. Patent 6,207, 694('694).

4. See col.2, lines 15-31 for polyethylene glycol (PEG), which reads on the claimed organic bulking agent. See examples for claim 7. See col.2, lines 36-46 for claim 8. The specification does not define the meaning of " condition" and it is the examiners position that the patent, which discloses shampoo for the control of ectoparasites, reads on the term " condition". The patent '152 does not teach the limitations of claims 2-3 wherein the concentration of the bulking agent is greater than 20% or greater than 50% or the pharmaceutically active agent as antifungal agents of claims 9, 12 or the specific antifungal agent of claim 13 or the specific surfactant of claim 16. All the examples in the patent teach water content grater than 20 %. However the patent at col.2 suggests the water content less than 20%. This is obtained when one skilled in the art adds the higher values for active ingredient, anionic surfactant, and polyhydric alcohol. The WO document teaches the concentration of the bulking agent PEG as 40-80%. The WO document also teaches non- aqueous compositions. See the examples. The patent '694 teaches antidandruff compositions using the antifungal agent at the paragraph bridging cols. 2-3, and also the specific sodium laureth sulfate, specific antifungal agent of claim 13. The patent also teaches foam booster which is Betaine under example 1. With respect to claim 15 limitations optimizing the water content is within the ken of the skilled chemist.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare compositions of '152 and increase the concentration of the PEG of the patent to greater than 20% and combine with anti fungal agent for the control of dermal

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infection. The motivation to use higher concentration of PEG stems from the teaching of WO document that at higher concentration the PEG can dissolve the active ingredients so that better fungicidal properties are exhibited and the PEG also acts as penetration enhancer. This is a prima facie case of obvious ness.

***Response to Amendment***

5. The declaration filed under 37 CFR 1.132 filed 8/17/05 is insufficient to overcome the rejection of claims 1-6, 8-10, 12-16 and 18-22 based upon over the combination of U. S. Patent '152 and WO 87/04617('617) and U. S. Patent 6,207, 694('694) as set forth in the last Office action because: for the following enumerated reasons:

I. The declaration compared sample A (instant application) with samples B and C drawn to example 3 of patent 5,866,152. *Sample A did not have water since the claims are drawn to “a substantially non-aqueous liquid shampoo... wherein the water content is less than 20% by weigh of said concentration”, where as samples B and C have water content (emphasis added).*

II. Applicants compared example 3 from patent '152 instead of example 1 which is also closer to instant application with respect to bulking agent, which is PEG 400. This was used in sample A. Note that the bulking agent can be PEG or propylene glycol. PEG400 was tested for sample A where as propylene glycol was used for comparison. The patent also uses both these bulking agents.

III. The testing is not commensurate with the scope of claims. Note that the bulking agent tested in sample A is PEG 400 and the active agent is limited to specific fungal agent, which is clotrimazole.

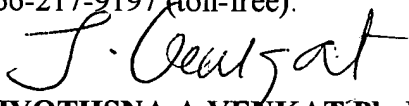
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Therefore the declaration is unpersuasive to overcome the 103 rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A. VENKAT Ph. D whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30: 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THURMAN K. PAGE can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**JYOTHSNA A VENKAT Ph. D**  
**Primary Examiner**  
**Art Unit 1615**

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